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10/800,380	03/12/2004	Miguel Acosta	52028/RVW/A789	8844
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CHRISTIE, PARKER & HALE, LLP			ALI, SHUMAYA B	
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			3743	

DATE MAILED: 02/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/800,380

Applicant(s)

ACOSTA, MIGUEL

Examiner

Shumaya B. Ali

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 17 October 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-16 and 18-20 is/are pending in the application.
- 4a) Of the above claim(s) 16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-16 and 18-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: detailed action.

## DETAILED ACTION

### *Response to Amendment*

In response to the office action mailed on 7/12/05, the applicant has added new claims 18-20, and withdrawn claim 17, currently claims 1-16, 18-20 are pending.

### *Response to Arguments*

1. **Applicant's arguments regarding claims 1-8 filed 10/17/05 have been fully considered but they are not persuasive.**
2. The statement regarding non-analogous argument presented on page 7, lines 18-20, is fully considered, however not persuasive since the applicant's **claimed invention** is **"a fitting"**, which according to the Webster's dictionary definition is the degree of precision with which surfaces are adjusted or adapted to each other in a machine or collection of parts. Therefore, Morgan's reference object 4 as disclosed in figures 1-2 used for the ground of rejection is considered valid, since object 4 is precisely adapted to a tubing 12.
3. The Applicant additionally stated on page 7, lines 6-8, that "the invention describe a fitting for retrofitting to a tracheostomy tube", however the underlined limitation is considered recitation of the indented use, which do not hold patentable weight (a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim).
4. Regarding "the cited reference does not teach nor suggest the limitation of a fitting for a tracheostomy tube having an outlet portion with at least one side opening" (page 7 lines 25-26): a

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labeled figure 1, see attachment below has been provided to indicate all limitations of fitting are disclosed in the prior art reference to Morgan.

5. As to claims 1-8, 35 USC 102 (b) rejection set forth using reference to Morgan US Patent 838,434 is retained. The Applicant is directed to a revised rejections to claims 1-8 under 35 USC 102 (b) provided below clarifying how structures of Morgan's reference anticipates limitations cited in claims 1-8.

6. Applicant's arguments with respect to claims 9-16 have been considered but are moot in view of the new ground(s) of rejection.

7. Claims 18-20 rejections under 35 U.S.C. 112, first paragraph, mailed on 12/29/2005 have been withdrawn.

***Claim Rejections - 35 USC § 112***

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 18 and 20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **As to claim 18, recitation "air flow aperture which lies in a plane substantially perpendicular to the length of the outlet structure" (lines 4-5), "the sleeve being arranged.....air flow communication with the tube end air flow aperture" (lines 7-11), and**

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as to claim 20, recitation “a plane transversely.....of the tracheostomy tube from the air flow aperture” (lines 3-6) are not found in the disclosure.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**Claims 1-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Morgan US Patent 838,434.**

10. As to claim 1, Morgan discloses a fitting (see labeled fig.2 reference objects 4,11, and 12) for retrofitting to a tracheostomy tube comprising: an inlet portion (see labeled fig.2) for attachment to an outlet structure of the tracheostomy tube; and an outlet portion (see labeled fig.2) for extending from the outlet structure of the tracheostomy tube, wherein the outlet portion is connected to the inlet portion (see fig.2), and wherein the outlet portion comprises at least one side opening (see fig.2, page 1 lines 75-76, “perforated” reads on “openings”).

11. As to claim 2, Morgan discloses the tracheostomy tube fitting of claim 1, wherein the outlet portion comprises a plurality of rows of side openings and a plurality of columns of side openings (see labeled fig.2 reference object 4 has a plurality of side opening, see also page 1 lines 75-76)

12. As to claim 3, Morgan discloses the tracheostomy tube fitting of claim 2, wherein each row is offset from an adjacent row and wherein each column is offset from an adjacent column

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(perforated casting 4 as depicted in fig.2 has row /column that are offset from an adjacent row/column).

13. As to claim 4, Morgan discloses the tracheostomy tube fitting of claim 1, further comprising a filter (fig.2 reference object 7, page 1 lines 78-80) attached to the outlet portion for filtering air that enters the fitting through the at least one-side opening.

14. As to claim 5, Morgan discloses a fitting (see labeled fig.2 reference objects 4,11, and 12) for retrofitting to a tracheostomy tube comprising: a hollow cylinder (fig.2 reference object 4; page 1 lines 83-84 recites “a sponge may be placed inside the casting 4”, therefore, the casting 4 is considered “hollow” since it has space to hold a sponge) having an inner diameter, an outer diameter (regarding “inner diameter” and “outer diameter”, a hollow cylinder inherently has an inner diameter consisting the perimeter inside the cylinder and an outer diameter consisting the perimeter outside of the cylinder) , an inlet end opening (fig.2, an inlet end opening is covered by a cover 5) and an outlet end opening (fig.2, an outlet end opening is covered by a cover 6) the cylinder further comprising: an inlet portion (see labeled fig.2), for attachment to an outlet structure of the tracheostomy tube, wherein the inlet portion comprises the inlet end opening (see labeled fig.2); and an outlet portion (see labeled fig.2) for extending from the outlet structure of the tracheostomy tube, wherein the outlet portion is connected to the inlet portion (see labeled fig.2), and wherein the outlet portion comprises the outlet end opening (see labeled fig.2) and at least one side opening (see fig.2, page 1 lines 75-76, “perforated” reads on “openings”) that extends from the inner diameter to the outer diameter (fig.2 depicts a “perforated” casting 4, therefore the perforation is considered

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**holes extending through the casting, thereby extending from the inner diameter to the outer diameter of the casting.)**

15. **As to claim 6, Morgan discloses the tracheostomy tube fitting of claim wherein the outlet portion comprises a plurality of rows of side openings (see labeled fig.2) that extend from the inner diameter to the outer diameter and a plurality of columns of side openings (see labeled fig.2) that extend from the inner diameter to the outer diameter**

16. **As to claim 7, Morgan discloses the tracheostomy tube fitting of claim 6, wherein each row is offset from an adjacent row and wherein each column is offset from an adjacent column (perforated casting 4 as depicted in fig.2 has row /column that are offset from an adjacent row/column).**

17. **As to claim 8, Morgan discloses the tracheostomy tube fitting of claim 5, further comprising a filter (fig.1 reference object 7) attached to the outlet portion for filtering air that enters the fitting through the at least one-side opening.**

**Claims 9-10, 13-14,18, and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Colavita US Patent No. 2,491,647**

18. **As to claim 9, Colavita discloses a tracheostomy tube (figs. 1-9, reference object 10, see also col.2 line 8) comprising: an inlet structure (12) for insertion into a patient's trachea; and an outlet structure (18) for extending from an opening in the patient's neck, wherein the outlet structure is connected to the inlet structure (see fig.2), and wherein the outlet structure comprises at least one side opening (see fig.2).**

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19. As to claim 10, Colavita discloses the tracheostomy tube of claim 9, wherein the outlet structure comprises a plurality of rows (see fig.2) of side openings and a plurality of columns (see fig.2) of side openings.

20. As to claim 13, Colavita discloses a tracheostomy tube (figs. 1-9, reference object 10, see also col.2 line 8) comprising: an inlet structure (12) for insertion into a patient's trachea; and an outlet structure (18) for extending from an opening in the patient's neck, wherein the outlet structure is connected to the inlet structure (see fig.2), and wherein the outlet structure comprises an inner diameter, an outer diameter (regarding "inner diameter" and "outer diameter", outlet structure 18 has is considered a hollow tube, see labeled fig.6 and a hollow tube inherently considered to have an inner and outer diameter) , an inlet end opening (see labeled fig.6, reads on "open top end", see col.3 lines 4-5) and at least one side opening (see fig.2) that extends from the inner diameter to the outer diameter (see labeled fig.6),

21. As to claim 14, Colavita discloses the tracheostomy tube of claim 13, wherein the outlet structure comprises a plurality of rows (see labeled fig. 6) of side openings that extend from the inner diameter to the outer diameter and a plurality of columns (see labeled fig.6) of side openings that extend from the inner diameter the outer diameter.

22. As to claim 18, Colavita discloses an occlusion preventing fitting (figs. 1-9, reference object 10, see also col.2 line 8) arranged for connection to an outlet structure (fig.3, 12) of a tracheostomy tube, which outlet structure comprises a substantially cylindrical tube terminal portion (see fig.3) defining a tube end air flow aperture ("a tube end air flow aperture" is considered the end opening of tube 12 that is in communication with 16 allowing mucous to flow into 16, see col.3 lines 27-35) which lies in a plane substantially perpendicular to the length



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of the outlet structure (see **fig.6**), the fitting comprising: a sleeve (18) having opposite open ends (see labeled **fig.6**) and having a substantially cylindrical sleeve wall (see labeled **fig.6**) through which is defined at least one sleeve wall opening (see **fig.2**), the sleeve being arranged to be engaged at one end see (**fig.1**, “one end” being connected to a tube 10) thereof around the outlet structure of the tracheostomy tube with the other end (**fig.1**, “other end” opposite to “one end”) of the sleeve spaced beyond the tube end air flow aperture relative to the tracheostomy tube and with the sleeve wall opening positioned toward the tracheostomy tube from the other end of the sleeve in effective air flow communication with the tube end air flow aperture (see **figs.2 and 3**).

23. As to **claim 20**, Colavita discloses an occlusion preventing tracheostomy tube having an outer end structure (**fig.3, 12**) which is located outside a trachea in use of the tracheostomy tube, the outer end structure having an air flow aperture (“a tube end air flow aperture” is considered the end opening of tube 12 that is in communication with 16 allowing mucous to flow into 16, see col.3 lines 27-35) at an outer end (where 18 connects the end opening of tube 12) of the tube which lies substantially in a plane transversely of the tracheostomy tube (see **fig.1**) and also defining at least one air flow opening laterally (see **fig.2**) into the tracheostomy tube at a location along the outer end structure of the tracheostomy tube from the air flow aperture (see labeled **fig.6**).

***Claim Rejections - 35 USC § 103***

24. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**Claims 11-12, and 15-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Colavita US Patent No.838, 438 as applied to claims 9-10, and 13-14 above, and further in view of Morgan US Patent 838,434.**

**25.** As to claim 11, Colavita discloses all claimed limitations as applied to claims 9 and 10 except for wherein each row is offset from an adjacent row and wherein each column offset from an adjacent column. However, such structure was well known in the art at the time of the invention. Morgan in figures 1 and 2 teaches a respirator with a filter proper (reference object 4, see also page 1 lines 75-80) having plurality of rows and column where each row is offset from an adjacent row and each column is offset from an adjacent column (see attached fig.2).

Colavita discloses a perforated sheet 18, which reads on the applicant's "outlet structure" and "perforated" reads on "side openings" used for allowance of a comparatively wide perimeter clearance interval for free passage of air for the wearer in breathing (see col.3 lines 1-4).

Similarly, Morgan's filter proper (4) is used for drawing air into the casting to be filtered and provided to the user of the respirator. Notice, regardless of the perforation alignment seen in the two reference, the perforations in either case are used to meet a common goal, which is to introduce breathable air to a user of the tracheostomy tube of Colavita or respirator of Morgan, therefore the perforations are considered capable of preventing airway obstruction of the user by bringing air into the user. **Therefore, it would have been obvious to one of ordinary skills in the art to substitute the perforation alignment of Colavita in view of Morgan in order to include opening/perforation with offsetting rows and columns as a matter of design choice.**

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26. **As to claim 12, Colavita do not disclose** the tracheostomy tube of claim 9, further comprising a filter attached to the outlet structure for filtering air that enters the tracheostomy tube through the at least one-side opening. However such limitation (“filter”) was well known in the art at the time the invention was made. Morgan in figures 1 and 2 teaches a respirator with a perforated casting (4) (“outlet structure”) and a filter material (7) covering the casting (see page 2, lines 21-22). **Therefore, it would have been obvious to one of ordinary skills in the art at the time of the invention to add a filter in view of Morgan to the outlet structure (18) of Colavita for the purposes of purifying incoming air.**

27. **As to claim 15, Colavita does not disclose** the tracheostomy tube claim 14, wherein each row is offset from an adjacent row and wherein each column is offset from an adjacent column. However, such structure was well known in the art at the time of the invention. Morgan in figures 1 and 2 teaches a respirator with a filter proper (reference object 4, see also page 1 lines 75-80) having plurality of rows and column where each row is offset from an adjacent row and each column is offset from an adjacent column (see attached fig.2). Colavita discloses a perforated sheet 18, which reads on the applicant’s “outlet structure” and “perforated” reads on “side openings” used for allowance of a comparatively wide perimetetric clearance interval for free passage of air for the wearer in breathing (see col.3 lines 1-4). Similarly, Morgan’s filter proper (4) is used for drawing air into the casting to be filtered and provided to the user of the respirator. Notice, regardless of the perforation alignment seen in the two reference, the perforations in either case are used to meet a common goal, which is to introduce breathable air to a user of the tracheostomy tube of Colavita or respirator of Morgan, therefore the perforations are considered capable of preventing airway obstruction of the user by bringing air into the user.

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**Therefore, it would have been obvious to one of ordinary skills in the art to substitute the perforation alignment of Colavita in view of Morgan in order to include opening/perforation with offsetting rows and columns as a matter of design choice.**

28. **As to claim 16, Colavita does not disclose** the tracheostomy tube of claim 13; further comprising a filter attached the outlet structure for filtering air that enters the tracheostomy tube through the at least one-side opening. However such limitation (“filter”) was well known in the art at the time the invention was made. Morgan in figures 1 and 2 teaches a respirator with a perforated casting (4) (“outlet structure”) and a filter material (7) covering the casting (see page 2, lines 21-22). **Therefore, it would have been obvious to one of ordinary skills in the art at the time of the invention to add a filter in view of Morgan to the outlet structure (18) of Colavita for the purposes of purifying incoming air.**

**Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Colavita US Patent No.838, 438**

29. **As to claim 19, Colavita discloses** the occlusion preventing fitting according to claim 18 in which plural openings (see fig.2) are defined through the sleeve wall at locations spaced around the sleeve (see labeled fig.6), **however does not disclose the sleeve is “flexible”**. As to “flexible”, the applicant has not established criticalities regarding why a “flexible” sleeve is critical to the invention. **Therefore, it would have been obvious to one of ordinary skills in the art to consider the constructive material of the sleeve as a matter of design preference, therefore further consider Colavita’s sleeve 18 which is fashioned from perforated sheet material (see col.2 lines 56-57) to meet the “flexible” limitation.**

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**Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Colavita US Patent No.838, 438 in view of Ancerwicz US Patent No. 3,585,997**

30. **As to claim 19, Colavita discloses the occlusion preventing fitting according to claim 18 in which plural openings (see fig.2) are defined through the sleeve wall at locations spaced around the sleeve (see labeled fig.6), however does not disclose the fitting is “flexible”.** However, at the time of the invention a flexible fitting used with tracheal tube was well known in the art. Ancerwicz teaches a tracheostomy device (see abstract) with a flexible (see col.3 lines 32-33, 41-43) receptacle/bag (“fitting”). **Therefore, it would have been obvious to one of ordinary skills in the art at the time the invention was made to modify the sleeve of Colavita in view of Ancerwicz in order to construct the sleeve “flexible” as a matter of design preference since Ancerwicz teaches in col.4 lines 52-59 that the receptacle or bag can be constructed from alternative materials. Additionally, it would have been obvious to one of ordinary skills in the art to use a “flexible” fitting that would allow bending for the purposes of easy removal and attachment of the fitting from/to the tube.**

### *Specification*

31. The amendment filed on 10/17/05 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: **As to claim 18, recitation “air flow aperture which lies in a plane substantially perpendicular to the length of the outlet structure” (lines**

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4-5), "the sleeve being arranged.....air flow communication with the tube end air flow aperture" (lines 7-11), and as to claim 20, recitation "a plane transversely.....of the tracheostomy tube from the air flow aperture" (lines 3-6) are not found in the disclosure.

Applicant is required to cancel the new matter in the reply to this Office Action.

32. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: **as to claims 18-19, recitation "sleeve" is not found in the specification.**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shumaya B. Ali whose telephone number is 571-272-6088. The examiner can normally be reached on M-F 8:30-4:30.

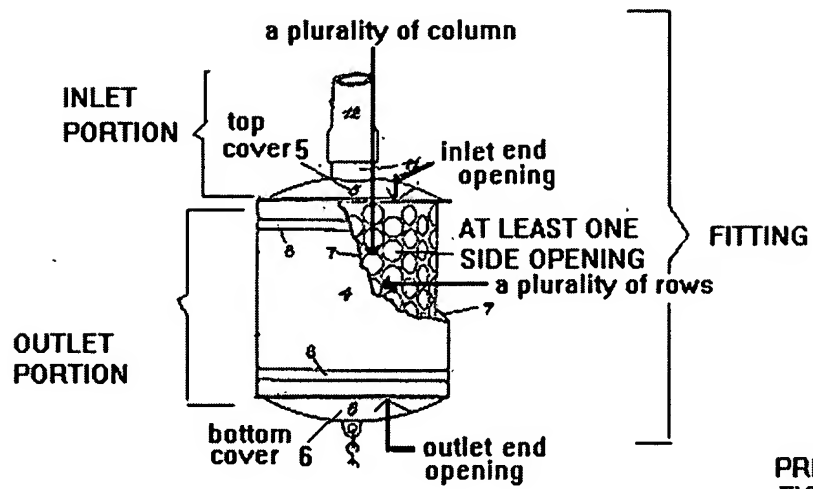
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on 571-272-4791. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

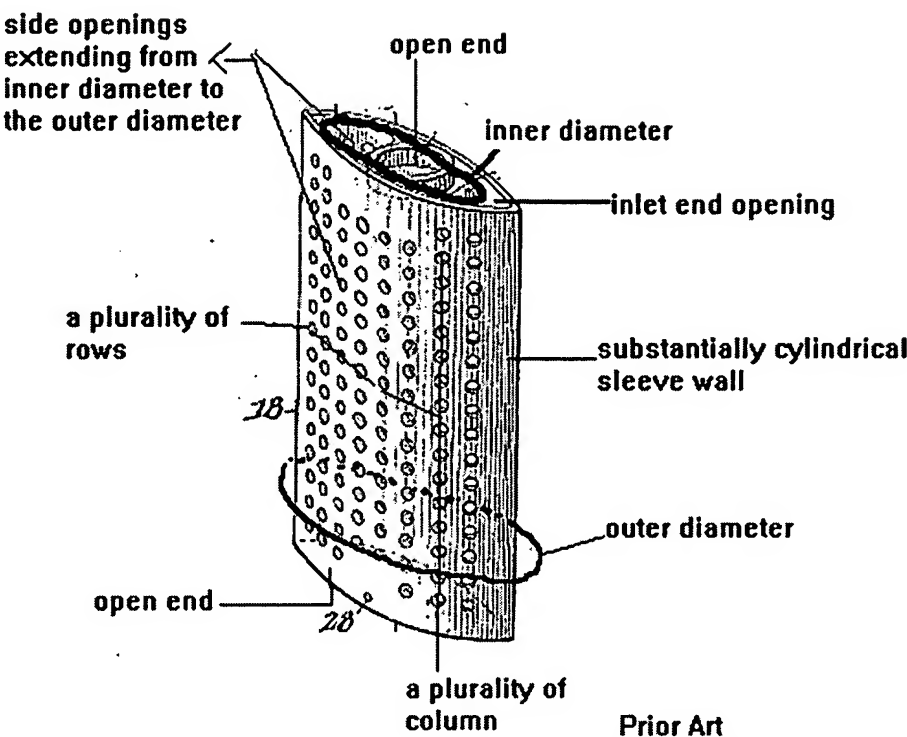
Henry Bennett  
Supervisor Patent Examiner  
Art Unit 3743

Shumaya B Ali  
Examiner  
Art Unit 3743

Art Unit: 3743



PRIOR ART  
FIG.2  
No. 638,434.  
J. MORGAN.



*FIG. 6.* Prior Art  
COLAVITA  
2,491,647